TENNESSEE GENERAL ASSEMBLY
FISCAL REVIEW COMMITTEE

FISCAL MEMORANDUM

HB 717 – SB 777

April 10, 2018

SUMMARY OF ORIGINAL BILL: Requires the Commissioner of the Department of Health (DOH), on or before January 15, 2018, to report to the Health Committee of the House of Representatives and the Health and Welfare Committee of the Senate, on the impact of recent legislation regulating and licensing pain management clinics in reducing the abuse of opioids in Tennessee. The Commissioner is required to make recommendations for any needed legislation to address issues raised by opioid abuse.

FISCAL IMPACT OF ORIGINAL BILL:

NOT SIGNIFICANT

SUMMARY OF AMENDMENT (016900): Deletes all language after the enacting clause. Declares that a nonresidential office-based opiate treatment facility includes, but is not limited to, stand-alone clinics, treatment resources, individual physical locations occupied as the professional practice of a prescriber or prescribers licensed pursuant to Title 63, or other entities prescribing products containing buprenorphine, or products containing any other controlled substance designed to treat opiate addiction by preventing symptoms of withdrawal to 25 percent or more of its patients "or", rather than "and", to 150 or more patients. Declares that "nonresidential office-based opiate treatment facility" does not include any facility that meets the definition of a nonresidential substitution-based treatment center for opiate addiction.

Requires the Commissioner of the Department of Mental Health and Substance Abuse Services (DMHSAS), by January 1, 2019, to revise rules for nonresidential office-based opiate treatment facilities to be consistent with state and federal law and to establish:

- standards for determining what constitutes a high dose of the opioid employed in treatment at a nonresidential office-based opiate treatment facility;
- protocols for initiating or switching a patient at a nonresidential office-based treatment facility to a high dose of the opioids employed in treatment; and
- protocols for initiating periodic prescriber-initiated and led discussions with patients regarding patient readiness to taper down or taper off the opioids employed in treatment.

Requires the Commissioner of DMHSAS, beginning in 2020, to review the rules for nonresidential office-based opiate treatment facilities by September 30 of each even numbered year and submit the rules for nonresidential office-based opiate treatment facilities to each health-related board that licenses any practitioner authorized by the state to prescribe the

products for the treatment of an opioid use disorder as defined in the Diagnostic and Statistical Manual of Mental Disorders and to the Board of Pharmacy.

Requires each health related board (HRB) to review the rules and enforce the rules with respect to that board's licensees and to post the rules on the licensing board's website.

Requires the Commissioner of DMHSAS to provide a copy of any emergency rules developed to the chairs of the Health Committee of the House of Representatives and the Health and Welfare Committee of the Senate at the time the rules are submitted to the HRB. Further requires the Commissioner of DMHSAS to provide a copy of any rule developed to the chairs of the Health Committee of the House of Representatives and the Health and Welfare Committee of the Senate at the same time the text of the rule is made available to the Government Operations Committees of the Senate and the House of Representatives for purposes of conducting the review required by Tenn. Code Ann. § 4-5-226 to afford the opportunity for the appropriate committees to comment on the rule.

Declares that a violation of rules for nonresidential office-based opiate treatment facilities will be grounds for disciplinary action against a practitioner licensed under Title 63 by the board that licensed that practitioner.

States that beginning July 1, 2018, the licensing fee for a nonresidential office-based opiate treatment facility is $1,500 per year. On or after July 1, 2019, the DMHSAS may revise the fee by rule. Authorizes the DMHSAS to apply a re-inspection fee of $500 to a nonresidential office-based opiate treatment facility.

Requires the Commissioner of the DMHSAS, in collaboration with the Commissioner of the Department of Health (DOH), to revise the nonresidential buprenorphine treatment guidelines to be consistent with state and federal law and establish protocols for initiating periodic prescriber initiated and led discussions with patients regarding patient readiness to taper down or taper off opioids employed in treatment.

Requires a healthcare practitioner to submit the dispensing of buprenorphine products in the controlled substance database. Exempts a practitioner when reporting the dispensing of buprenorphine products would conflict with 42 CFR part 2.

Prohibits the dispensing of buprenorphine products, notwithstanding any other law, by any person or entity unless the dispensing is done by a nonresidential office-based opiate treatment facility, with the approval of the DMHSAS, a nonresidential substitution-based treatment center for opiate addiction, a pharmacy licensed under Title 63, Chapter 10, or a hospital licensed under Title 33, or Title 68, Chapter 11. Clarifies this subsection does not apply to the administering of buprenorphine products as otherwise permitted by law.

Requires the DOH to identify the top 20 prescribers who have unique DEA numbers of buprenorphine products or equivalent products in the previous calendar year, or if implemented more frequently for the relevant time period as determined by the department, from the data available in the controlled substances database.

Requires, at the discretion of the DOH, each prescriber and each collaborating physician or supervising physician, as appropriate, of an advanced practice registered nurse and physician assistant who appear on the lists of the top 20 prescribers of buprenorphine products in all of the counties combined having a population of less than 50,000, according to the 2010 federal census or any subsequent federal census in the relevant period of time shall submit to the department within 15 business days through registered mail or electronic mail an explanation justifying the amounts of controlled substances prescribed in the relevant period of time by the prescriber demonstrating that these amounts were medically necessary for the patients treated and that, for advanced practice registered nurses and physician assistants, the collaborating physician or supervising physician, as appropriate, had reviewed and approved the prescribing amounts.

Requires the DOH, in consultation with the controlled substance database, to identify licensed prescribers whose prescribing patterns of controlled substances represent statistical outliers in addition to top prescribers and high-risk prescribers identified pursuant to this section after the completion of the a study and no later than July 31 of each year. Further requires the DOH to inquire of the appropriate licensing board concerning any action taken against a prescriber identified by the DOH and each board is to respond within 30 days concerning the status of any action or lack of action against an identified prescriber.

Requires each HRB to also report on the total numbers of prescribers disciplined each year and the general categories of discipline imposed on the prescribers, including consent agreements, as well as reasons for declining to exercise discipline.

Requires the Commissioner of the DOH to report a summary of the data concerning prescribers identified under this subsection, including a summary of any disciplinary action taken or pending by a licensing board against a prescriber, to the chairs of the Health and Welfare Committee of the Senate and the Health Committee of the House of Representatives.

Requires the Comptroller of the Treasury to complete a study of the incidence of significantly statistically abnormal prescribing patterns by prescribers licensed under Title 63 and the disciplinary response of the licensing boards to those prescribers. The Comptroller shall report findings and recommendations of the study to the chairs of the Health and Welfare Committee of the Senate and the Health Committee of the House of Representatives.

Creates a task force composed of representatives from the Board of Medical Examiners, the Board of Osteopathic Examination, the Board of Dentistry, the Board of Podiatric Medical Examiners, the Board of Optometry, the Board of Nursing, and the Board of Medical Examiners' Committee on Physician Assistants. The task force must create a uniform minimum disciplinary action if a healthcare practitioner treats a human patient with an opioid and that healthcare practitioner's licensing board or agency finds that the healthcare practitioner engaged in a significant deviation or pattern of deviation from sound medical judgment, which shall be binding on each board and committee. Declares the task force will terminate upon the later of July 1, 2019, or the effective date of a permanent rule establishing the uniform minimum disciplinary action pursuant to this section.

FISCAL IMPACT OF BILL WITH PROPOSED AMENDMENT:

Increase State Revenue – $525,000/Recurring

Increase State Expenditures – $26,300/One-Time
$1,000,300/Recurring

Assumptions for the bill as amended:

- Based on information provided by the DMHSAS, the proposed legislation will result in an increase in the amount of licenses issued to nonresidential office-based opiate treatment facilities as the legislation reduces the threshold that an office-based opiate treatment facility must meet to apply for a license.
- Under current law, a facility must be treating at least 50 percent of its patients for opiate addiction, and the facility must have at least 150 patients being so treated, for it to qualify as a nonresidential office-based treatment facility. Pursuant to this legislation, a facility must be treating at least 25 percent of its patients for opiate addiction, or the facility must have at least 150 patients being so treated, for it to be considered a nonresidential office-based treatment facility.
- It is estimated 350 new licenses will be issued at a cost of $1,500 per license.
- The recurring increase in state revenue is estimated to be $525,000 (350 licenses x $1,500) in FY18-19 and subsequent years.
- Based on information provided by the DMHSAS, the proposed legislation cannot be accommodated within existing resources. The DMHSAS will require six additional surveyors to handle the estimated increase in licenses due to the new provisions in the proposed legislation and one licensure surveyor manager to oversee the additional surveyors.
- The one-time increase in state expenditures associated with the additional positions is estimated to be $8,400 in computer cost.
- The recurring increase in state expenditures associated with the additional positions is estimated to be $504,471 ($322,300 salaries + $104,371 benefits + $46,700 professional services + $3,900 supplies + $27,200 travel).
- Based on information provided by the DOH, the proposed legislation cannot be accommodated within existing resources. The DOH will require one legal assistant to monitor and track cases monthly; two consultants, one physician and one nurse practitioner to determine whether the provider's actions were not consistent with the standard of care for treating patients for substance use disorder; and one attorney for enforcement purposes.
- The one-time increase in state expenditures associated with these additional positions is estimated to be $17,900 ($7,100 computer cost + $10,800 office furniture).
- The recurring increase in state expenditures associated with these additional positions is estimated to be $495,862 ($369,708 salaries + $90,354 benefits + $31,600 administrative cost + $1,800 communication cost + $2,400 supplies).

- The total one-time increase in state expenditures as a result of this legislation is estimated to be $26,300 ($8,400 + $17,900).
- The total recurring increase in state expenditures as a result of this legislation is estimated to be $1,000,333 ($504,471 + $495,862).
- The task force will be composed of representatives from the health related boards. It is assumed these representatives will serve on the task force during regularly-scheduled business hours. Any expenditures incurred by the task force are estimated to be not significant.
- Pursuant to Tenn. Code Ann. § 4-29-121, all health related boards are required to be self-supporting over a two-year period.
- The Board of Medical Examiners had an annual surplus of $382,952 in FY15-16, an annual deficit of $4,714 in FY16-17, and a cumulative reserve balance of $2,855,288 on June 30, 2017.
- The Board of Osteopathic Examiners had an annual surplus of $102,565 in FY15-16, an annual surplus of $91,307 in FY16-17, and a cumulative reserve balance of $794,231 on June 30, 2017.
- The Board of Dentistry had an annual surplus of $253,054 in FY15-16, an annual surplus of $211,016 in FY16-17, and a cumulative reserve balance of $4,317,446 on June 30, 2017.
- The Board of Podiatric Medical Examiners had an annual surplus of $50,474 in FY15-16, an annual surplus of $21,595 in FY16-17, and a cumulative reserve balance of $308,788 on June 30, 2017.
- The Board of Optometry had an annual surplus of $22,205 in FY15-16, an annual surplus of $23,883 in FY16-17, and a cumulative reserve balance of $694,558 on June 30, 2017.
- The Board of Nursing had an annual surplus of $1,408,207 in FY15-16, an annual surplus of $1,564,664 in FY16-17, and a cumulative reserve balance of $9,273,968 on June 30, 2017.
- The Board of Physician Assistants had an annual surplus of $90,688 in FY15-16, an annual surplus of $44,841 in FY16-17, and a cumulative reserve balance of $718,718 on June 30, 2017.

CERTIFICATION:

The information contained herein is true and correct to the best of my knowledge.

Krista M. Lee RNC

Krista M. Lee, Executive Director

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